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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/673,884      | 10/23/2000  | Kiyozo Asada         | 1422-443P           | 6983             |

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EXAMINER

SIEW, JEFFREY

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1637

DATE MAILED: 02/10/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/673,884

Applicant(s)

ASADA ET AL.

Examiner

Jeffrey Siew

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 10-15 and 24-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 16-23, 31-34 is/are rejected.
- 7) ☒ Claim(s) 19, 20 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### **Location of Application**

1. The location of the subject application has changed. The subject application is now located in Group 1630, Art Unit 1637, and is assigned to Patent Examiner Jeffrey Siew.

### ***Election/Restrictions***

2. Applicant's election with traverse of Group I in Paper No. 8 is acknowledged. The traversal is on the ground(s) that the parent PCT application, no lack of unity was made. Moreover the special technical feature defines the contribution which each invention makes over the prior art. As heparin in its use as DNA synthesis reaction enhancer are disclosed in the prior art. This is not found persuasive because the claims do not read solely on heparin but also other well known compounds in the prior art such as pectin and DNA (see Sigma Biochemicals and organic Compound Catalog 1995 (pp. 522-524, 775, 1456-1457). The lack of novelty provides the basis of lack of unity requirement over the all claims. Although the restriction is maintained, the election of species is withdrawn. It is noted that the Group I contained a typographical error. Claims 1-9,16-23,31-34 are drawn to Group I. Claims 10-15,24-30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No.7.

The requirement is still deemed proper and is therefore made FINAL.

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***Double Patenting***

3. Claims 19 & 20 are objected to under 37 CFR 1.75 as being a substantial duplicate of claims 22 & 23. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 1-9,16-18,21,31-34 are rejected under 35 U.S.C. 102(e) as being anticipated by Barnes (US6,410,277 June 25, 2002).

Barnes teach a formulation and kit of thermostable DNA polymerases in which one polymerase has 3'-5' exonuclease activity and another second polymerase does not have 3'-5' exonuclease polymerase (see abstract). They teach *pyrococcus furiosus* polymerase which posses the 3'5' exonuclease activity. They teach performing PCR with these compostion which amplify DNA (see col.4 line 41).

The applicant is reminded that further limitations on one of the alternatives in the parent claim may not eliminate the reading of the claim on the other alternatives, in particular see claims 5-9.

5. Claims 1-9,16-19,22,31-34 are rejected under 35 U.S.C. 102(e) as being anticipated by Lee et al (US6,495,350 Dec. 17, 2002).

Lee et al teach formulation and method of DNA polymerase composition of two polymerases—one with 3'-5' exonuclease and the other polymerase with reduced 3' exonuclease (see col. 3 lines 40-55).

While the second polymerase is reduced, both polymerases still have exonuclease activity.

### ***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

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the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 20 & 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al (US6,495,350 Dec. 17, 2002) in view of

Lee et al teach formulation and method of DNA polymerase composition of two polymerases—one with 3'-5' exonuclease and the other with reduced 3' exonuclease (see col. 3 lines 40-55). They teach selection of one or more polymerase for amplifying (see col.4 lines 45-50 & col. 9).

Lee et al do not teach one alpha polymerase and one non alpha polymerase.

Sorge et al teach an alpha type polymerase and polymerase II or non alpha polymerase of *P. furiosus* (see col. 29 lines 60-65) which both show 3' exonuclease activity..

One of ordinary skill in the art would have been motivated to combine Lee et al's teaching of combination polymerases with Sorge et al's teaching of alpha and non alpha polymerase to amplify DNA . It would have been prima facie obvious to apply Sorge et al's teaching of the alpha and non alpha polymerase both with exonuclease activity in order to proofread the extension reactions.

## SUMMARY


7. No claims allowed.

### CONCLUSION

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Siew whose telephone number is (703) 305-3886 and whose e-mail address is Jeffrey.Siew@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner is on flex-time schedule and can best be reached on weekdays from 6:30 a.m. to 3 p.m. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703)-308-1119.

Any inquiry of a general nature, matching or filed papers or relating to the status of this application or proceeding should be directed to the Tracey Johnson for Art Unit 1637 whose telephone number is (703)-305-2982.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Center numbers for Group 1600 are Voice (703) 308-3290 and Before Final FAX (703) 872-9306 or After Final FAX (703) 30872-9307.

  
**JEFFREY SIEW**  
**PRIMARY EXAMINER**

February 5, 2003